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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,386	10/16/2001	James F. Zucherman	KLYC-01055US1	4255

23910 7590 08/27/2003

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EXAMINER

BUI, VY Q

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,386

Applicant(s)

ZUCHERMAN ET AL. *cd*

Examiner

Vy Q. Bui

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-15, 17-26 and 28-53 is/are pending in the application.
- 4a) Of the above claim(s) 42-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-15, 17-26, 28-41 and 47-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-2, 7, 13-15, 21-22, 28-29, 34-37, 47-49 are rejected under 35 U.S.C. 102(e) as being anticipated by BURNETTE (4,592,579).

As to claims 1-2, 7, 13-15, 21-22, 28-29, 34-37 and 47-49, BURNETTE (Figs. 4, 29-30) discloses device 43 with handle portion/ proximal portion of device 43, elongated body/mid portion of device 43, conical tapered curved tip 50. Notice that curved tip 50 is conical or curved tip 266 gradually and continuously increases from a first diameter to a second diameter as recited in the claims.

3. Claims 1-2, 7, 13-15, 21-22, 28-29, 34-37, 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by ZUCHERMAN et al. (5,836,948).

The applied reference has a common inventor (ZUCHERMAN) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

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As to claims 1-2, 7, 13-15, 21-22, 28-29, 34-37, 47-48, ZUCHERMAN (Figs. 40; col. 9, lines 46-50) discloses cannula 258 with handle portion/proximal portion 268, elongated body/mid portion of cannula 258, conical tapered curved tip 266. Notice that curved tip 266 is conical or curved tip 266 gradually and continuously increases from a first diameter to a second diameter as recited in the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The applied reference has a common inventor (ZUCHERMAN) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

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5. Claims 3-6, 9-12, 17-20, 23-26, 30-33, 38-41 and 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over NICHOLS et al. (5,361,766) in view of ZUCHERMAN et al. (5,836,948).

As to claims 3-6, 9-12, 17-20, 23-26, 30-33, 38-41, NICHOLS discloses a device that has an elongated body (20) with a solid tapered curved tip (22) on one end and a handle (10) on the opposite end, as most clearly illustrated in Figure 2. NICHOLS discloses substantially all the limitations of the claims, except for a conical curved tip and the size of the curved tip dilator as claimed. ZUCHERMAN (Fig. 40; col. 9, lines 46-50) shows cannula 258 having curved conical tip for insertion/dilation into the space between the spinous processes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify NICHOLS curved tip (22) to have a conical configuration as recited in the claim, as the modification would provide a curved conical tip configuration to the NICHOLS device and this configuration would effect the insertion/dilation a space between two spinous processes. The NICHOLS device is sized for being inserted into areas of the spine. It would have been an obvious matter of design choice to form the device to have the dimensions set forth in the claims, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

As to claim 49, NICHOLS discloses substantially all the limitations of the claim, but does not disclose a curved conical tip. However, ZUCHERMAN (Fig. 40; col. 9, lines 46-50) shows cannula 258 having curved conical tip for insertion/dilation into the space between the spinous processes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify NICHOLS curved tip (22) to have a conical configuration as recited in the claim, as the modification would provide a curved conical tip configuration to the NICHOLS device and this configuration would effect the insertion/dilation a space between two spinous processes.

As to claims 50-53, NICHOLS and ZUCHERMAN include substantially all the limitations of the claims except for the size of the curved tip dilator. The device is sized for being inserted into areas of the spine. It would have been an obvious matter of design choice to form the device to have the dimensions set forth in the claims, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 9-15, 17-26, and 28-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

08/22/2003